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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,540	04/12/2004	Aron D. Rosenberg	04712/050002	1791
21559	7590	10/26/2010		
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110				
EXAMINER				
AZPURU, CARLOS A				
ART UNIT		PAPER NUMBER		
1617				
NOTIFICATION DATE		DELIVERY MODE		
10/26/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

### Office Action Summary

**Application No.**

10/822,540

**Applicant(s)**

ROSENBERG ET AL.

**Examiner**

Carlos A. Azpuru

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3, 4, 7-38, 40, 41, 44-80, 82 and 84-106 is/are pending in the application.
- 4a) Of the above claim(s) 38, 40, 41, 44-80 and 82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 6 is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 7-37 and 84-106 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt is acknowledged of the amendment and petition filed 06/21/2010..

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

It is noted that the reference cited in the previous action was provided by applicant with a European Search which indicated it as a "X" reference. After review, it was agreed that the reference should be cited for its teaching to fully differentiate between that claimed invention, and that of the instant claims. It was also noted that the incorrect serial number was cited for this PG-PUB document, and the exact document could not be located. The rejection was made based on the EP search, with the hope that applicant would provide the correct serial number. The correct serial number was provided by Todd Armstrong, so that the rejection will be restated with the citations in this action. A PTOL-892 will also be provided with the correct serial number for the PG-PUB document to Lee Dosuk et al.

The following rejection is restated in this action:

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3, 4, 7-37, 84-106 are rejected under 35 U.S.C. 102(b) as being anticipated by US 2003/049329 A1 (Lee Dosuk et al).

Lee Dosuk et al disclose an osteoinductive powder comprising a demineralized bone matrix (DBM) and a calcium phosphate powder. The percentage of demineralized bone matrix is within the claimed percentage, as is the size of the DBM particles. Biologically active agents are also included. The ratio of calcium to phosphate is also set out fibrous embodiments having the instantly claimed characteristics.(see {0001}, [0058], [0115]—[0117], and [0151]. Particle size of at most 500 um is cited at [0091].

The instant claims are anticipated by Lee Dosuk et al.

### ***Response to Arguments***

Applicant's arguments filed 06/21/2010 have been fully considered but they are not persuasive.

Applicant argues that the reference does not teach a particle size of less than about 850 um. However, at [0091], the reference discloses a maximum particle size of 500 um. Therefore, the reference reads on the newly amended claims.

The following rejection is made in view of applicant's newly submitted amendment:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,3,4, 7-37 and 84-106 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

While applicants have amended the claims to read on a size of "less than 850 um" from one of the dependent claims into the independent claims, support for the open ended range is not found. The table at pages 44 and 45 supports the upper limit, but also indicates a lower limit of 53 um. This is consistent with the specification at page 6, lines 22-23. As such, the open ended range is considered new matter. Correction is requested.

Claims 1,3,4, 7-37 and 84-106 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a particle size of between 53  $\mu\text{m}$  – 850  $\mu\text{m}$ , does not reasonably provide enablement for all particles “less than 850  $\mu\text{m}$ ”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant clearly states at page 7, lines 5-7 that even the lower limit was not previously thought to have orthopedic applications in the prior art. Applicants appear to be the first to recognize the lower limit as applicable to such uses. As such, the lower limit of the range of particles should be 53  $\mu\text{m}$  as only this is enabled by the specification.

### ***Conclusion***

No claims are allowed.

Claims 38, 40, 41, 44-80 and 82 are withdrawn. Rejoinder will be considered once allowance is indicated.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydown G. Sajjadi can be reached on (571) 272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos A. Azpuru/  
Primary Examiner, Art Unit 1617

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